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| 09/326,285 | 06/07/1999 | JENNIE BIH-JIEN SHEN | BB-1137 | 4005 |

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| EXAMINER |
|---|
| EINSMANN, JULIET CAROLINE |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1634 | |

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Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/326,285 | SHEN, JENNIE BIH-JIEN | |
| | Examiner | Art Unit | |
| | Juliet C Einsmann | 1634 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *8/26/02, 9/23/02, and 10/16/02* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *172-176* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *172-176* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 June 1999* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

### *Continued Prosecution Application*

1. The request filed on 9/23/02 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/326285 is acceptable and a CPA has been established. An action on the CPA follows.

2. This action is written in response applicant's correspondence submitted 8/26/02, 9/23/02, and 10/16/02. The paper filed 8/26/02 contained an after-final amendment to claims 172-176 which was entered. In addition the paper contained arguments which were not considered because they relied on exhibits that were not timely filed. These arguments are addressed herein. The papers filed 9/23/02 contained an amendment canceling all non-elected claims. The paper filed 10/16/02 contained a 132 declaration. Claims 172-176 remain pending and are examined herein. Applicant's amendments and arguments have been thoroughly reviewed, but are not fully persuasive for the reasons that follow. Any rejections not reiterated in this action have been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### *Priority*

3. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 172-176 of this application. Priority is not granted to provisional application 60/088987 because this application does not discuss methods for improving carcass quality.***Drawings***

4. New corrected drawings are required in this application because of the objections noted on the PTO 948 mailed with paper number 12. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in **ABANDONMENT** of the application.

### *Election/Restrictions*

5. The elected claims contain subject matter that is drawn to a non-elected invention (i.e. SEQ ID NO: 2, SEQ ID NO: 11, SEQ ID NO: 58, and SEQ ID NO: 59). Prior to allowance, non-elected subject matter will be required to be deleted from the claims. In the interest of compact prosecution, applicant is requested to remove this subject matter in response to this office action.

### *Claim Rejections - 35 USC § 112*

### *Second Paragraph*

6. Claims 172-176 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 172-176 are indefinite over the recitation of the phrase "carcass quality improving amount" because it is not clear exactly what amount of an animal feed would constitute a carcass

quality improving amount. The specification provides no guidance in the determination of such an amount, and therefore the metes and bounds of this claim are unclear.

Claims 172-176 are indefinite over the recitation "or a functionally equivalent subfragment of the isolated nucleic acid fragment encoding a corn delta-9 stearoyl ACP desaturase" or "or a functionally equivalent subfragment of the isolated nucleic acid fragment encoding a corn delta-12 desaturase" because it is not clear what function is required to be a "functionally equivalent" subfragment. That is, does the subfragment have to encode an active corn delta-9 stearoyl ACP desaturase or is the sharing of some other function with the isolated nucleic acid fragment included in this language, and if the sharing of some other function is included, what function?

***First Paragraph***

7. Claims 172-176 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 172-176 are drawn to methods of improving animal carcass quality by feeding an animal a "carcass quality improving" amount of animal feed derived from transgenic plants which comprise chimeric genes as listed in the claims. These claims are broadly drawn in that they encompass methods for improving the carcass quality of any animal, and they do not specifically indicate the amount of feed necessary to effect the goal of improving any aspect of carcass quality in any possible animal. Further, neither the claims nor the specification offer

guidance as to how to measure carcass quality or what aspect of carcass quality would be improved by the consumption of the animal feed derived from the plants described in the claims.

The specification exemplifies transgenic plants that have high stearic acid content and transgenic plants that have high oleic acid content (Example 7). The specification generally defines a "carcass quality improving amount" an amount necessary to improve carcass quality (p. 20), and generally recites the instant methods (p. 26). The specification provides no specific feeding regimes, nor does the specification provide any working examples wherein carcass quality is improved in any animals. The specification provides no guidance as to which animals will be expected to have their carcasses improved, during what part of the feeding regime the animals should be fed the plants comprising the chimeric genes, how much feed would be "a carcass quality improving amount" or how the ordinary practitioner should measure the improvement in carcass quality. Indeed, other than the mention of improving animal carcass quality on pages 20 and 26 of the specification, the specification is devoid of any guidance as to the improvement of carcass quality. The determination of such factors would require extensive experimentation with a wide variety of animals, and such experimentation would in itself be inventive.

The prior art does not offer any guidance as to the effects of feeding any animal feed derived from the processing of the transgenic corns described herein. A series of DuPont Specialty Grains reports released in 1998 disclosed the effects of feeding animals OPTIMUM High Oil Corn. These reports do not provide detailed disclosure of the composition of the OPTIMUM corn, other than referring to it as high oil corn. A later paper by Soderlund et al. ("Benefits of Feeding OPTIMUM High Oil Corn to Finishing Beef Cattle

Introduction/Nutritional Considerations, Nutritional Insights: Vol. 2, No. 1, 1999) teach that the OPTIMUM corn has a larger germ portion which displaces a portion of the endosperm resulting in higher oil content in the kernels because the germ is where the kernel's oil is located. Thus, unlike the transgenic plants of the instant invention, which exhibit an altered distribution of oils, the plants discussed in the DuPont Specialty grains reports have a greater amount of total oil. Nonetheless, this series of reports indicates that the effects of changes in feeding regimes on animal carcass quality are unpredictable, because the reports demonstrate positive effects on carcass quality for some animals but not for others when they are fed the OPTIMUM corn. For example, in research report AFG6090 (1998) results on feeding studies in steers demonstrate that the changes in feeding regime resulted in a higher percentage of choice carcasses, but no effects on carcass characteristics were observed. Report AFG6024 provided results where no changes in carcass quality of pigs were observed when fed with the high oil corn. Report AFG6071 presents results which indicate that steer fed the high oil corn had higher marbling scores and higher quality grades (i.e. improved carcass quality), and Report AFG6088 found that the high oil corn can replace regular corn in a diet for steer, but only improved carcass quality in a higher feed quantity of high oil corn. In hens and turkey, no improvement in carcass quality was observed when the feeding regime included the high oil corn (AFG6063 and AFG6124). Thus, though for some animals improvement in carcass quality can be observed using high oil corn, this observation is not universal for all animals.

Due to the broad nature of the claims, the lack of guidance in the specification or in the prior art, the high level of unpredictability with regard to the effects of feeding regimes on animal carcass quality, the lack of working examples, and the high level of experimentation

necessary to determine the methodology necessary to practice the claimed invention, it is concluded that undue experimentation would be required to practice the claimed invention.

Furthermore, with regard to the plants that are described to be used as animal feed, the does not reasonably provide enablement for the claimed plants. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the plants commensurate in scope with these claims.

The specification teaches corn plants which have high stearic acid content (compared to wild type) in corn grains after transformation with chimeric constructs that contain either the anti-sense (pBN262) or sense (pBN264 or pBN427) strands of a truncated corn delta-9 desaturase (a truncated version of the full length SEQ ID NO: 9) (see example 7, pages 44-47). The specification also teaches corn plants with high oleic acid content (compared to wild type) in corn grains after transformation with chimeric constructs that comprise a near full length fad2-1 coding region with the ATG out of frame (pBN257 (SEQ ID NO: 58) or construct pBN428) (see example 7, pages 48-49). The specification discusses possible mechanisms for producing plants with high stearic acid content and high oleic acid content, but does not exemplify such plants.

The specification does not teach any general mechanism by which the introduced nucleic acids are effecting the fatty acid content of the plants. The specification does not teach a plants with a broad range in changes in fatty acid composition, only plants with high stearic acid content or high oleic acid content. The specification also does not teach plants which comprise both of the desaturases in which altered lipid content is observed.

It is highly unpredictable which nucleic acid sequences would result in the alteration of the lipid profile of plants. That is, although transformation of the plants with the corn

deasturases described in the claims may be possible, the effect of using, for example, a full length sense copy of corn delta-9 stearoyl ACP desaturase on a plant is highly unpredictable. The specification teaches plants in which sense and anti-sense nucleic acids encoding corn delta-9 stearoyl ACP desaturase are introduced into plants, and in both instances the resulting plant displayed high saturate fatty acid composition. The mechanism by which this occurs is unclear, and therefore, it is not possible to predict the effect that adding other nucleic acids to the plants would have on the plant. Inhibition of the functioning of the native enzyme by an introduced nucleic acid is expected to be sequence dependent, and the specification provides no guidance as to how the instant nucleic acids can be altered so as to produce plants with similar alterations in fatty acid composition. The claims are broadly drawn to include the use of plants transformed with any portion of nucleic acids encoding a desaturase with 80% identity to the disclosed desaturase or with any functional fragment thereof. However, the specification provides no guidance as to how the nucleic acids of the examples can be modified and still have the same effect on a plant upon transformation of the plant with the nucleic acid. The experimentation necessary to determine other plants would require the production of many plants using many different nucleic acids, both sequence variants of the disclosed nucleic acids and fragments of the disclosed nucleic acids, assaying the produced plants for lipid content and analyzing the results for an association between different nucleic acids an changes in lipid content. Furthermore, claims 174 and 176 encompass transgenic plants that have both the corn delta 9 stearoyl ACP desaturase ant the corn delta 12 desaturase, yet the example which discusses such a plant is prophetic. The effects of the inclusion of both transgenes in a plant are unknown, and thus it is impossible to know how such a plant would effect animal carcass quality.

Finally, it is to be noted that each of the claims have portions which recite the use of full length or partial corn oleosin promoters, wherein those promoters have at least 80% identity with or hybridize under moderately stringent conditions to instant SEQ ID NO: 19 or 38-49. Some embodiments within the claims particularly recite that the chimeric constructs also contain a shrunken 1 intron/exon. The specification teaches at pages 40-41 in Example 6 that the full length promoter (that is SEQ ID NO: 19) provides non-detectable or minimal activity, and that none of SEQ ID NO: 38-49 demonstrate the ability to promote expression of a heterologous gene absent the presence of the shrunken 1 intron/exon. Yet, the claims specifically recite constructs that are absent this element and the claims specifically recite the use of SEQ ID NO: 19 and related sequences as promoters. The specification is not enabling for the use of such constructs. Furthermore, with regard to the changes in sequence that are encompassed within the identity and hybridization language, the ability of a promoter to function is highly sequence specific. The art teaches repeatedly that mutations in a critical region of a promoter element can destroy the ability of a construct to function in promotion. For example, Pietrzkowski *et al.* (Experimental Cell Research, 193, 283-290 (1991)) teaches that when synthetic promoters were produced wherein the sequence of an enhancer element was mutated, little to no promotion was observed from the constructs where the promoter was mutated (see for example Figure 6). Chan *et al.* (Plant Molecular Biology 46 :131-141, (2001)) teach that mutation in a critical XXIII element of the GAPB promoter abolished transcription completely (Figure 6), while mutations in other elements did not abolish activity (Figure 6). Thus, it is evident that it is highly unpredictable how promoter elements will respond to even very minor sequences changes. In addition, the order that promoter elements occur in a construct has an effect on the functionality

of the promoter. Omilli *et al.* (Molecular and Cellular Biology, June 1986, p. 1875-1885) teach that the relative arrangement of promoter elements is a critical factor contributing to the activity of the promoter (ABSTRACT, for example). Yet the specification provides no guidance as to how instant SEQ ID NO: 38-49 can be modified yet still retain their ability to promote transcription of a heterologous sequence when paired with the shrunken 1 intron/exon.

Due to the lack of guidance in the specification, the high level of experimentation that would be required to make other plants with altered lipid content, and the high level of unpredictability with regard to which nucleic acids would be useful for producing such plants, undue experimentation would be required to produce animal feed from plants as broadly claimed.

8. Claims 172-176 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The current claims are drawn to a method which improving animal carcass quality which comprise feeding the animal feed derived from transgenic plants comprising chimeric molecules which comprise nucleic acids encoding a corn delta-9 stearoyl ACP desaturase which has an amino acid sequence with 80% identity to SEQ ID NO: 9, nucleic acids encoding a corn delta-12 desaturase wherein the nucleic acid has 80% sequence identity to SEQ ID NO: 1, or functional fragments of either of these two nucleic acids. Further, the claims include plants comprising corn oleosin promoters with 80% identity to SEQ ID NO: 19 or 38-49 or which hybridize to SEQ ID NO: 19 and 38-49 under moderate stringency conditions. This large genus is represented in

the specification by only SEQ ID NO: 9, SEQ ID NO: 1, or SEQ ID NO: 19 and 38-49, as appropriate. Further, the response of the plants produced largely depends on the functionality of the sequence introduced. Thus, applicant has express possession of only single species in a genus which comprises hundreds of millions of different possibilities.

With regard to the written description, all of these claims encompass nucleic acid sequences different from those disclosed in the specific SEQ ID No:s which, for claims 172-176 include modifications by permitted by the % identity language or the "functionally equivalent subfragment" language for which no written description is provided in the specification. Furthermore, the claims all recite that the nucleic acids at issue are "corn" nucleic acids, and the specification has provided no guidance as to how to identify, of all of the nucleic acids encompassed within the breadth of these claims, which of these are particularly "corn" nucleic acids. Especially with regard to the functionally equivalent subfragment language, the mechanism by which the introduced nucleic acids act in plants is unknown, and therefore the "function" of the nucleic acids in the plants is unknown.

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that

> "...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

In the instant application, only the SEQ ID NO: 1 is described. Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

> "...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention

being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description which would demonstrate conception or written description of any plants containing chimeric genes modified by addition, insertion, deletion, substitution or inversion with the disclosed SEQ ID Nos but retaining correlative function in the claimed product.

**Response to Remarks**

Applicant's remarks concerning each of the reiterated rejections have been considered but are not persuasive. The arguments provided in the response filed 8/26/02 and in the declaration filed 10/16/02 are duplicative and are addressed together. It is noted that these papers both cite a number of references without providing a proper IDS. Some of these references were utilized in the rejections provided herein, and thus they are cited on the enclosed 892. If applicants wish for the other cited references to appear on the front of any eventually issued patent, a proper IDS which complies with all applicable rules should be provided for the examiner to sign.

*112 2nd paragraph*

Applicant argues that the rejection in view of the term "carcass quality improving amount" is unwarranted in view of the arguments and additional information submitted. However, this is not persuasive. While the term "carcass quality" may be well defined in the prior art, and methods for feeding animals and experimenting with feeding regimes may be known in the prior art, the "carcass quality improving amount" described herein is not defined in either the prior art or the specification. The specification lacks any definition as to how much or how little of the instant animal feed derived from the processing of corn grain constitutes a

carcass quality improving amount. In a literal way, the metes and bounds of this claim are undefined. The skilled practitioner has no way of knowing from the disclosure in the specification (or the prior art) how much animal feed derived from the processing of corn grain from the disclosed transgenic plants would be within the metes and bounds of these claims. The purpose of the claim is to clearly define the boundaries of the invention, and in this case, the claim provides no boundary for the amount of feed that is being fed to animals in the only active process step of the claim. The rejection is maintained. New rejections are also set forth.

*112 1st paragraph*

Applicant cited a number of references which demonstrate feeding trials focusing on the effects of oil composition on animals to demonstrate that those skilled in the art know how to adjust feeding regimens and that to the extent any experimentation is needed it is undue. First, it is noted that many of the articles provided by applicant were not prior art references (for example Hansen et al. 2001, Gatlin et al. (2002)),or could not be determined to be prior art references due to ambiguity of the dates on the references (DuPont Specialty Grains Reports AFG7004, AFG5002, AFG6065, the FeedLot article which was updated 02 April 2001, and the Nutritional Insights articles). Nonetheless, none of these get at the fundamental issue herein, which is that the instant specification provides only a starting off point for the determination of a "carcass quality improving amount" of the animal feed "derived" from the transgenic plants described in the instant claims. Clearly, from the teachings of the prior art, the amount of fat an animal consumes can have some effect on carcass quality, and that the skilled artisan could undertake feeding experiments for any type of animal to determine if animal feeds derived from the instant transgenic plants might improve some aspect of carcass quality in subjects. This issue is not at

dispute. At dispute is whether the instant application provides sufficient guidance to support a method which results in an improvement in animal carcass quality upon feeding with the transgenic plants recited in the instant disclosure. Applicants claims are not limited to supplementing oil compositions in animal feed or simply changing the distribution of oil in an animal feed, they are directed towards feeding animals parts of transgenic corn plants and obtaining some (any) improvement in some aspect of carcass quality.

The declaration states that "the data and literature presented herein demonstrates that carcass quality can be reproducibly improved through feeding regimens, and particularly, that feeding of high-oleic grain improves carcass quality (paragraph 2)." However, the declaration does not provide any evidence that the instant specification provides sufficient guidance for one to carryout the instantly claimed methods. Indeed, the declaration does not particularly address the instant invention, but instead relies on the disclosure of the art, some prior art and some post-filing date art. The feeding studies presented concerning OPTIMUM corn are related only in that they are feeding studies looking at variation in oil content in animal diets. The OPTIMUM corn plants have more oil, not different oil. Furthermore, as noted in the rejection, some of these trials demonstrated success in changing carcass quality and some did not. There appears to be no general formula for determining how much of a particular animal feed will be a carcass quality improving amount.

Applicant asserts at page 12 of the 8/02 response (paragraph 5 of the declaration) that it is possible to show that dietary fat and pork carcass quality are related. This assertion is not disputed. Rather, it is disputed that the instant specification provides enough enabling disclosure to carry out a method for improving animal carcass quality, as is presently claimed. No guidance

for carrying out such a method is provided in the specification. Instead, the entire enablement of the claimed methods for improving animal carcass quality is reliant on supposed knowledge in the prior art and of the skilled artisan and what applicant is attempting to characterize as further routine experimentation.

A relevant court case in this issue is Genentech Inc. v. Novo Nordisk A/S (CAFC) 42 USPQ2d 1001. In this case, a method for using cleavable fusion expression to make hGH was found to lack enabling support from the specification. The patent in question provided general guidance as to how to use cleavable fusion expression to make hGH, but "not describe in any detail whatsoever how to make hGH using cleavable fusion expression. For example, no reaction conditions for the steps needed to produce hGH are provided; no description of any specific cleavable conjugate protein appears." This is similar to the instant application which provides general guidance and relies on the teachings of the prior art to suggest methods for improving animal carcass quality by feeding animals a carcass quality improving amount of a transgenic plant can be determined without undue experimentation. In the Genentech case, the court goes on to state,

> "Genentech's arguments, focused almost exclusively on the level of skill in the art, ignore the essence of the enablement requirement. Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable... However, when there is no disclosure of any specific starting material or of any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. This specification provides only a starting point, a direction for further research."

The declaration vaguely refers to two feeding trials which utilize combinations of typical corn and high oleic corn, but do not provide sufficient information on these trials in order for the

examiner to evaluate them, nor is any statistical analysis of the results provided. Furthermore, in order for such data to overcome the instant rejection, it would have to be closely mirroring guidance for improving animal carcass quality provide in the specification. However, this is not possible, since such guidance is entirely lacking.

Applicant is further referred to MPEP 716.09 which states, "Evidence to supplement a specification which on its face appears deficient under 35 U.S.C. 112 must establish that the information which must be read into the specification to make it complete would have been known to those of ordinary skill in the art." In the instant case, the information which must be read into the specification is the guidance as to how to practice the claimed method, for example, guidance as to the carcass quality improving amount of feed, the aspects of carcass quality to be improved, and the particular animals whose carcasses can be improved. The MPEP further states, "Affidavits or declarations presented to show that the disclosure of an application is sufficient to one skilled in the art are not acceptable to establish facts which the specification itself should recite."

The remarks provided in the Attorney's arguments and in the declaration with regard to the Machev et al. reference are persuasive and this reference has been removed from the enablement rejection.

Applicant draws the Examiner's attention to the fact that the specification describes (1) transgenic plants with high saturate fatty acid composition in grain (2) transgenic corn with a high oleic acid content in the grain and (3) transgenic corn with high levels of saturated and oleic acid in kernels, thus concluding that the specification and examples show one of ordinary skill in the art how to practice the claimed invention. This statement is problematic on a number of

grounds. First, it is noted that the specification only actually demonstrates the production of plants in the category of (1) and (2). The third type of plants were never made, the examples in the specification are only prophetic. Even in light of the making of these plants, however, the specification does not provide any guidance related to the instantly claimed invention, which is drawn to a method for improving animal carcass quality, as has been discussed above.

With regard to the scope of enablement for the production of transgenic plants, Applicant's arguments do not adequately address the discussion of the Wands factors provided in the enablement rejection. The conclusion that undue experimentation would have been necessary to make transgenic plants commensurate in scope with those used in the instant method claims is was made because of the lack of guidance in the specification, the high level of experimentation that would be required to make other plants with altered lipid content, and the high level of unpredictability with regard to which nucleic acids would be useful for producing such plants, undue experimentation would be required to produce animal feed from plants as broadly claimed. Applicant has demonstrated for only a small portion of the broad range in the claims the making of the transgenic plants used in the claimed invention. The fact that both sense and anti-sense constructs to the same gene yield the same effect (high saturate fat composition) in the transgenic plants underscores the assertion that the state of the art with regard to the production of transgenic plants displaying this particular phenotype is highly unpredictable. While it is not necessary that applicant understand the mechanism of the action in these transgenic plants, such a relationship would be helpful to help overcome the concerns regarding the unpredictabilty of the claimed invention. The specification provides only two working examples which use a particular nucleic acid sequence to effect the goal of increasing

saturate fatty acid composition in transgenic corn. The specification provides no guidance as to how those sequences could be modified yet still yield plants with the same phenotype, nor does the specification provide any guidance as to how a plant with high saturate fatty acid composition could be used to improve the carcass quality of animals. In light of each of these factors, it was concluded by the examiner that undue experimentation would be necessary to make transgenic plants commensurate in scope with those described in the elected claims, and further to practice the methods of the claimed invention.

Further pending is a 112 1st paragraph rejection directed to the lack of written description of the claimed invention. Applicant points out that the specification defines "functionally equivalent subfragment" and discusses percent identity language. However, these definitions do not overcome the fact that the claims are not supported by adequate written description. The claims provide a structure for the nucleic acids to be used in the transformation, but the claims do not provide an adequate functional language relating to that structure. Applicant argues that eh claims recite a structure and correlate with a function- either a corn delta 12-desaturase or a corn delta-9 stearol ACP desaturase or a promoter. However, first, as noted in the written description rejection, the specification does not provide distinguish "corn" molecules from all of those within the scope of the claims. Furthermore, with regard to the asserted "function" language, the claims do not require that the encoded desaturase be active and possess activity, and in fact that specification states that such functional fragments only have to retain the activity to alter expression in a transgenic plant. This dichotomy of possible functions of the nucleic acids encompassed in the claims only underscores the point that there is not a clear structure function requirment in the claims. The same is true for the claimed promoters. Although the claims

recite that the nucleic acid molecules with homology to or that hybridize to instant SEQ ID NO: 19 or 38-49, this language is not a clear statement of function since even within this group SEQ ID NO: 19 was demonstrated to have no ability to promote transcription. Thus the claims embrace the use of nucleic acids that are not properly described with a structure-function relationship. Notwithstanding, even if the claims did include a proper structure function relationship to describe the nucleic acids, it is not clear that this language would be sufficient to overcome the rejections directed towards lack of enablement of the claimed invention.

***Conclusion***

9. No claims are allowed.

10. Nucleic acids consisting of SEQ ID NO: 19 and 38-49 are free of the prior art.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Einsmann whose telephone number is (703) 306-5824. The examiner can normally be reached on Monday through Thursday, 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Juliet C Einsmann
Examiner
Art Unit 1634

December 27, 2002

JEHANNE SOUAYA
PATENT EXAMINER
Jehanne Souaya
12/30/2002